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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,528	12/15/1999	SAVERIO CARL FALCO	BB1205-US-NA	7694
23906	7590	12/03/2003	EXAMINER	
E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/464,528	<b>Applicant(s)</b> FALCO ET AL.	
	<b>Examiner</b> Cynthia Collins	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2003 has been entered.

Claims 1-12 are cancelled.

Claims 13-24 are currently amended.

Claims 25-28 are newly added.

Claims 13-28 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

***Claim Rejections - 35 USC § 112***

Claims 13-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 22, 2002, and for the additional reasons set forth below.

Applicant argues that the rejection under 35 U.S.C. 112, first paragraph, should be withdrawn because the claim 13 has been amended to remove reference to the term subfragments (reply page 4).

The rejection is maintained first because nucleic acids that hybridize to SEQ ID NO:6 or SEQ ID NO:14 are not described, and because the structural elements of SEQ ID NO:6 and SEQ ID NO:14 that would be retained by hybridizing nucleic acids that retain promoter function are also not described.

The rejection is additionally applied to newly added claims 25-28, directed to a method of decreasing the expression of an endogenous gene in a plant cell by transforming a plant cell with a chimeric gene of claim 14. The claimed method is not described because the endogenous gene to be downregulated and the transforming construct are not described. The ability to transgenically decrease endogenous gene expression is dependent on the specific sequence of the targeted endogenous gene as well as sequences homologous thereto located in the transforming construct, yet the specification does not describe the structure of any construct that specifically decreases the expression of any particular endogenous gene in any species of plant cell.

Claims 13-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment having constitutive promoter activity comprising the nucleic acid sequence of SEQ ID NO:6 or of SEQ ID NO:14, as well as for methods of expressing sequences operably linked to said isolated nucleic acid fragment, does not reasonably provide enablement for isolated nucleic acid fragments which can hybridize to SEQ ID NOS:6 or 14 under stringent conditions, or for methods of decreasing the expression of endogenous genes in plant cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed May 22, 2002, and for the additional reasons set forth below.

Applicant's arguments filed October 28, 2002, have been fully considered but they are not persuasive.

Applicant argues that the rejection under 35 U.S.C. 112, first paragraph, should be withdrawn because the claim 13 has been amended to remove reference to the term subfragments (reply page 4).

The rejection is maintained first because the specification does not provide sufficient guidance for one skilled in the art to make and use hybridizing promoter sequences without undue experimentation. The disclosure does not provide sufficient guidance for obtaining hybridizing sequences that have promoter function, or for discriminating between functional and nonfunctional hybridizing sequences. Such guidance is necessary because the ability of a hybridizing sequence to function as a promoter is unpredictable, even where such a sequence is obtained using highly stringent conditions, because even minor changes in the length or sequence of a promoter, as would occur in sequences obtained even using highly stringent conditions, can alter or eliminate promoter

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function. Absent such guidance one skilled in the art would have to resort to testing all hybridizing sequences on a trial and error basis in order to distinguish between operative and inoperative embodiments of the numerous promoter variants that fall within the scope of the claims.

The rejection is additionally applied to newly added claims 25-28, directed to a method of decreasing the expression of an endogenous gene in a plant cell by transforming a plant cell with a chimeric gene of claim 14. The claimed method is not enabled because the specification does not provide guidance with respect to which endogenous gene to target for decreased expression, or how to decrease its expression. Such guidance is necessary because methods for decreasing the expression of endogenous genes in plant cells are unpredictable. For example, van der Krol et al. teach a method of decreasing the expression of an endogenous petunia chalcone synthase gene by transforming petunia cells with chimeric genes comprising chalcone synthase (CHS) coding sequences operably linked in an antisense orientation to a CaMV 35S constitutive promoter (Plant Molecular Biology, 1990, Vol. 14, pages 457-466). The full length CHS cDNA and CHS sequences encoding half-length or quarter-length RNA complementary to the 3' half of the CHS mRNA decreased the expression of endogenous CHS, whereas half-length RNA complementary to the 5' half of the CHS mRNA did not (page 460 Figures 1 and 2; page 461 Figure 3). See also Puchta et al. who review the long standing difficulties that have been encountered in developing methods for decreasing endogenous plant gene expression using chimeric genes designed for targeted gene replacement via homologous recombination, such as the inability to overcome extremely low gene targeting frequencies in plants by varying transformation methods, extending the length of homology in transferred DNA, and including negative selectable markers (Plant Molecular Biology, 2002, Vol. 48, pages 173-182, especially page 174). Absent guidance with respect to which endogenous gene to target and how to decrease its expression, it would require undue

experimentation for one skilled in the art to determine how to use a chimeric gene of claim 14 to decrease the expression of a particular endogenous plant gene.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method of decreasing the expression of endogenous gene in a plant cell by transforming a plant cell with the chimeric gene of claim 14. The chimeric gene of claim 14 comprises at least one heterologous nucleic acid fragment operably linked to the isolated nucleic acid fragment of claim 13 (a constitutive promoter). It is unclear what the at least one heterologous nucleic acid fragment is heterologous to, the isolated nucleic acid fragment of claim 13, or the endogenous gene whose expression is to be decreased. If the at least one heterologous nucleic acid fragment is heterologous to the endogenous gene, it is also unclear how the chimeric gene of claim 14 would decrease the expression of the endogenous gene in a plant cell. The specification suggests only two means by which the isolated nucleic acid fragment of claim 13 could be used in a chimeric gene to decrease gene expression, antisense and cosuppression. A chimeric gene used to decrease gene expression by antisense or cosuppression would ordinarily be understood to comprise a nucleic acid fragment homologous to the suppressed gene operably linked to a promoter.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC



AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
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